



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

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Gray Cary Ware & Freidenrich LLP  
Attention: David L. Rosen  
1625 Massachusetts Avenue NW, Suite 300  
Washington, DC 20036-2247

Docket No. 2004P-0373/CP1

Dear Mr. Rosen:

This is in response to your petition filed on August 20, 2004, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug product: Omeprazole Magnesium Delayed-release Capsules, 20 mg. The reference listed drug to which you refer in your petition is Prilosec OTC™ (Omeprazole Magnesium) Delayed-release Tablets, 20 mg, approved under NDA 21-229 held by AstraZeneca.

Your request involves a change in dosage form from that of the listed drug product (i.e., from tablets to capsules). The change you request is the type of change that is authorized under the Federal Food, Drug, and Cosmetic Act (Act).

We have reviewed your petition under Section 505(j) (2) (C) of the Act and have determined that it is approved. This letter represents the Food and Drug Administration's (FDA) determination that an ANDA may be submitted for the above-referenced drug product.

In addition, this petition and your waiver request were evaluated with respect to the "Pediatric Research Equity Act of 2003" (PREA). PREA requires that all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration include an assessment of the safety and effectiveness of the drug for the claimed indication in all relevant pediatric subpopulations unless the requirement is waived or deferred. Your pending ANDA suitability petition is affected by this Act because it is a petition for a change in dosage form. Omeprazole magnesium delayed-release tablets are labeled for over-the-counter use in patients 18 years of age and older. However, the prescription product, omeprazole delayed-release capsules, is adequately labeled for pediatric use. For patients less than 18 years of age it is more appropriate to use the prescription product omeprazole delayed-release capsules because it would require a physician's intervention for proper diagnosis and treatment, and for accurate dosing based upon the child's weight. Therefore, the FDA has determined that your proposed change in dosage form is subject to PREA; but has concluded that the requirements for PREA have already been met.

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Omeprazole Magnesium Delayed-release Capsules, 20 mg  
Gray Cary, Ware & Freidenrich, LLP

Under Section 505(j)(2)(C)(i) of the Act, the FDA must approve a petition seeking a change in dosage form that differs from the listed drug product unless it finds that investigations must be conducted to show the safety and effectiveness of the differing dosage form.

The FDA finds that the change in dosage form for the specific proposed drug product does not pose questions of safety or effectiveness because the uses, dose, and route of administration of the proposed drug product are the same as that of the listed drug product. The FDA concludes, therefore, that clinical investigations are not necessary to show safety or effectiveness in this instance. In addition, if shown to meet bioavailability requirements, the proposed drug product can be expected to have the same therapeutic effect as the listed reference drug product.

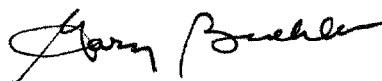
The approval of this petition to allow an ANDA to be submitted for the above-referenced drug product does not mean that the FDA has determined that an ANDA will be approved for the drug product. The determination of whether an ANDA will be approved is not made until the ANDA itself is submitted and reviewed by the FDA.

To permit review of your ANDA submission, you must submit all information required under Sections 505(j) (2) (A) and (B) of the Act. To be approved, the drug product will, among other things, be required to meet current bioavailability requirements under Section 505(j) (2) (A) (iv) of the Act. We suggest that you submit your protocol for this drug product to the Office of Generic Drugs, Division of Bioequivalence prior to the submission of your ANDA. During the review of your application, the FDA may require the submission of additional information.

The listed drug product to which you refer in your ANDA must be the drug product upon which you based this petition. In addition, you should refer in your ANDA to the appropriate petition docket number cited above, and include a copy of this letter in the ANDA submission. Please note that once an application is approved for a product that is the same as the subject of an approved petition, that drug product will be the listed drug. Thereafter, a petition may not be utilized as the basis for submission of an ANDA.

A copy of this letter approving your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,



Gary J. Buehler  
Director  
Office of Generic Drugs  
Center for Drug Evaluation and Research